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Fenestrated Aortic Endografts for Juxtarenal Aortic Aneurysm: Medium Term Outcomes

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Abstract *Aims:* The utility of fenestrated-endovascular aneurysm repair (FEVAR) remains uncertain. This study examines the medium term outcomes of patients undergoing FEVAR for asymptomatic juxtarenal abdominal aortic aneurysm (AAA).
Methods: Consecutive patients undergoing elective FEVAR for juxtarenal AAA at a single tertiary centre were studied between October 2005 and March 2010. Patients were followed up for at least six-months within a protocol including clinical examination, laboratory studies, CT and duplex imaging, and abdominal radiographs. Outcomes were assessed in terms of survival, target vessel patency and graft related complications.
Results: Twenty-nine patients were analysed on an intention to treat basis. There were 27 men and two women of median (range) age 74 (54—86) years. Mean (SD) aneurysm diameter was 68 (7) mm. Median (range) ASA score was 3 (2—4). No procedures required conversion to an open procedure, but one procedure was abandoned. Seventy-nine visceral vessels were perfused through a fabric fenestration or scallop. All vessels remained patent at completion angiography. No patients died within 30-days of surgery. During follow up there were four (14%) deaths at a median (range) of 17 (8—21) months after aneurysm repair. None of these deaths were aneurysm related. Eighteen (62%) patients suffered one or more graft related complications, of whom 11 (38%) required one or more early or late reintervention.
Conclusions: Fenestrated aortic endografts can be utilized safely in the management of juxtarenal AAA in patients at high-risk for open surgery. However, the rate of graft related complication and reintervention is high at medium term follow up.

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Introduction

Endovascular Aneurysm Repair (EVAR) has established itself as an effective treatment in the management of asymptomatic, large, infrarenal abdominal aortic aneurysm (AAA).[1,2] However, more than 50% of patients have aneurysm morphology that is unsuitable for conventional endovascular repair.[3] Of these, a significant proportion will have an inadequate length of normal infrarenal aorta above the aneurysm within which to achieve a proximal seal, and account for up to 15% of AAA.[4] Fenestrated endovascular aneurysm repair (FEVAR) was first described in 1999 as an endoluminal solution for patients with an inadequate infrarenal aortic neck.[5] Fabric fenestrations of the endograft, with or without bridging stents, permit perfusion of visceral branch vessels while achieving a secure proximal seal. Such devices are now commercially available and are challenging the established indications for EVAR.

Although a large number of fenestrated endoprostheses have been implanted into patients, there is a paucity of evidence to support the use of FEVAR. In the absence of randomised controlled trials, small cohort studies underpin the existing evidence base. Existing reports are generally from endovascular enthusiasts reporting favourable short-term outcomes.[6–10] The present series reports the medium term outcomes from a single centre, with the specific aim of highlighting the challenges faced in the implementation of a fenestrated aortic endograft programme.

Patients and Methods

A single-centre, retrospective, observational cohort study was performed at the Leicester Royal Infirmary, UK. This is a high-volume tertiary referral vascular surgical service performing, approximately, 100 conventional EVARs each year. Consecutive patients undergoing attempted repair of an intact juxtarenal or suprarenal AAA with a fenestrated endograft were accumulated over the period October 2005–June 2010 and studied on an intention to treat basis.

Patients were selected for FEVAR on the basis of a juxtarenal AAA of at least 55 mm in diameter, with a proximal neck too short for standard EVAR, but otherwise suitable anatomy for EVAR together with unsuitability for open aneurysm repair. Patients were deemed unsuitable for open surgery on the basis of co-morbidities or previous abdominal surgery with an abdomen too hostile for further laparotomy. Patients were classified using the American Society of Anaesthesiologists (ASA) guidelines.

Preoperative high-resolution computed tomography (CT) scans for all patients, and angiography obtained at the physician's discretion, were used to determine if the aneurysm morphology was suitable for FEVAR. Customised fenestrated devices based on the Cook Zenith system (William A. Cook Australia, Ltd., Brisbane, Australia) were designed on multiplanar reconstructions and centreline of flow calculations derived from CT scans. Diameters and lengths of the aorta and iliac arteries, and visceral vessel morphology were used to measure the relative positions of visceral vessels to match the fenestrations in a similar manner to prior publications.[11] Small (6 × 8 mm), large (>8 mm), or scalloped (located at the uppermost portion of fabric) fenestrations were included as options for the device design. All procedures were performed under general anaesthesia in a conventional operating room with mobile imaging equipment. Completion angiography was used to ensure freedom from endoleak, vessel patency and aneurysm exclusion. The first four cases in the series were undertaken under the mentorship of the multidisciplinary team from the Royal Liverpool Hospital, UK.[6]

Patients were followed up for at least six-months within a protocol which included clinical examination, laboratory studies, CT and duplex imaging, and abdominal radiographs. The current surveillance protocol entails anteroposterior and lateral plain X-rays, duplex ultrasound and CT aortography prior to discharge. Duplex ultrasound and CT scan at 3 months, plain X-rays and duplex ultrasound at 6 months and plain X-rays, duplex ultrasound and CT scan at 12 months and yearly thereafter. Diagnostic angiography was utilized selectively. Outcomes were assessed in terms of survival, target vessel patency, graft related complications and reintervention, in accordance with SVS reporting standards for EVAR.[12] An increase in aneurysm sac size of >5 mm was regarded as a complication.

Results

Patients

Twenty-nine patients were included within an intention to treat protocol. There were 27 men and two women of median (range) age 74 (54–86) years. The mean (SD) aneurysm diameter was 68 (7) mm and the median (range) ASA score was 3 (2–4). Three patients had undergone a failed attempt at open AAA repair at another centre prior to FEVAR. One patient was already established on haemodialysis prior to intervention. Patient comorbidity is shown in Table 1.

Endografts

A three-component system was utilized in all but one of the patients. In the remaining patient, an aorto uni-iliac system and contralateral iliac occluder device were used due to access difficulties. Seventy-nine visceral vessels were intended to be perfused through a fenestration or scallop, including 52 renal arteries, 25 superior mesenteric arteries (SMA) and 2 coeliac arteries. The most common configuration, two fenestrations for the renal arteries and a scallop fenestration for the SMA, was used in 19 patients. Three patients had a single renal fenestration, two required one renal fenestration with two scallops for the remaining renal and SMA, two required a single renal fenestration and a scallop for the other renal and one patient only needed a single scallop for a single renal artery. Two patients needed grafts with four fenestrations to also include the coeliac artery. None of the grafts incorporated an accessory renal artery.

Procedural details

None of the procedures required immediate conversion to an open repair. However, five (18%) patients suffered an intraoperative complication. In one patient with

Table 1 Comorbidity amongst 29 patients.

Comorbidity	Number of patients
Smoker/COPD	21 (72%)
Hypertension	15 (52%)
Ischaemic Heart Disease (MI or Angina)	13 (45%)
Hostile abdomen/Stoma	4 (14%)
Chronic Renal Failure (eGFR $<$ 60)	3 (10%)
Cardiac failure	3 (10%)
Cerebrovascular disease	2 (10%)

a four-fenestration graft, repair had to be abandoned completely as the mainbody of the endograft could not be manipulated to achieve correct orientation within the aorta. One patient was found to have an incorrect mainbody graft size and had to be rescheduled for completion of FEVAR two weeks later. In a further patient, the imaging equipment failed intraoperatively, and again this patient had to be brought back for completion of FEVAR four days later.

All but two of 49 fenestrations were reinforced with a stent, of which 29 were covered stents and 18 uncovered. All 47 stents were in renal arteries apart from one patient who had covered stents placed in the SMA and coeliac artery, and one patient who had a single uncovered SMA stent.

One patient suffered a renal artery perforation that required placement of a covered stent, and another patient had an acutely ischaemic lower limb due to common femoral artery thrombosis in a chronically diseased vessel. This patient required a common femoral thromboendarterectomy and patch closure to achieve revascularisation.

Apart from the patient in whom FEVAR was abandoned, all other patients had successful aneurysm exclusion alongside target vessel preservation on completion angiography.

Early postoperative outcomes

There were no deaths in-hospital or within 30-days of aneurysm repair. Eight patients were monitored in the intensive care unit postoperatively. All but one were discharged to the ward after one day, while the remaining patient stayed for two days. No patients required new postoperative renal replacement therapy. Median (range) length of hospital stay was three (1—12) days. The patient in whom FEVAR was unsuccessful was discharged after a day. Only one patient suffered an early postoperative graft related complication. In this patient, a covered renal stent was found to have occluded on the first postoperative day. Repeat renal angioplasty and stenting was performed with recovery of renal perfusion.

Late outcomes

Median (range) length of follow up was 20 (7—62) months. There were four deaths during follow up, at a median (range) of 17 (8—22) months after FEVAR. None of these deaths were aneurysm related. The patient with preoperative haemodialysis dependent renal failure died from complications of renal failure eight months after surgery. Causes of death and time from surgery are shown in Table 2.

Fourteen (48%) patients suffered one or more graft related complications following discharge from hospital. Two of these patients had already had a perioperative or early postoperative complication. One patient's SMA and another patient's renal artery thrombosed during follow-up. Both case were asymptomatic. The most common complications were renal stent fracture, stenosis or migration. Of the 29 covered stents, there were three renal stent migrations and three stent stenoses. Of the 18 uncovered stents, there were four stent fractures with stenosis, two stent fractures with vessel thrombosis and two stent stenoses. Within the series, there are six renal stent stenoses in five patients that are being managed expectantly.

Four (14%) patients had an increase in their aneurysm sac size $>$5 mm during follow up. One patient had types I, II and III endoleaks that have required intervention; the type III endoleaks needed renal stent angioplasty on one side and redo renal stenting on the other, the type I endoleak was treated with the liquid embolisation agent Onyx (Micro Therapeutics, Inc., CA, USA). Another patient had a type II endoleak treated with inferior mesenteric artery embolisation. A further patient has a probable type I endoleak and is awaiting intervention. The final patient had an indeterminate endoleak, but was found to be too frail for further investigation or reintervention, and was managed expectantly, eventually dying from pneumonia 12 months after diagnosis. There were two other type II and a type III endoleak without evidence of sac expansion. Types of complication are listed in Table 3.

Nine (32%) patients required one or more late reinterventions at a median (range) of seven (1—12) months. Types of reintervention are listed in Table 4. One patient in the series has required three reinterventions to treat type III endoleaks at each renal stent and a type I endoleak. Two patients have needed two reinterventions; one a renal stent angioplasty and iliac limb extension and the other has required repeated restenting of a fractured uncovered renal stent.

Discussion

Fenestrated endovascular aneurysm repair represents an attractive option for patients with aortic aneurysm morphology that is unsuitable for conventional EVAR. Feasibility has been demonstrated clearly and uptake of the technique has been compelling, with more than 2000 prostheses inserted worldwide.[9] However, the evidence base to support FEVAR is less persuasive at present. It is noteworthy

Table 2 Causes of death and time after FEVAR in four patients.

Cause of death	Time (months)
Stroke	22
Multiorgan failure following strangulated hernia	18
Pneumonia	15
Chronic renal failure	8

Table 3 Fourteen patients with one or more late graft related complication.

Complication	Number of patients
Renal stent fracture/stenosis (unilateral or bilateral)	9
Iliac limb stenosis/occlusion (unilateral or bilateral)	3
Target vessel loss (SMA x1, Renal x1)	2
Type III endoleak – junctional (unilateral or bilateral)	2
Type II endoleak with sac expansion	2
Type I endoleak	2

that a recent systematic review of the literature was only able to account for less than 25% of the devices that have been used.[13] Although the existing observational cohort studies stem from esteemed endovascular centres, that have been early adopters of the technology, the nature of publication bias may result in an unrealistic picture. To permit the rational, and evidence based, development of FEVAR as a therapeutic solution for juxtarenal AAA, there is a need for multicentre outcome data to be standardised, and collated centrally for meaningful analysis. Such a collaborative endeavour is already in place in the form of the GLOBAL collaborators on Advanced Stent-graft Techniques for Aneurysm Repair (GLOBALSTAR) project, and support of this initiative must be encouraged.[14]

The present data reports a non-randomised series of patients with large asymptomatic juxtarenal AAA with unfavourable comorbidity for open repair selected for FEVAR. Careful patient selection governed the series, which represents all patients ever treated with a fenestrated endograft from this centre. It therefore reflects the challenges experienced during the learning curve and the lessons learnt.

Procedural complications in the form of problems of equipment or device complications arose in three patients. The most salutary lesson stemmed from the patient in whom the endograft could not be adequately orientated. This patient had undergone a successful trial passage of a Lunderqvist stiff wire prior to surgery and been deemed suitable for FEVAR. However, the calibre of the fenestrated endograft resulted in an inability to manoeuvre the device within the aorta. The procedural vulnerability, due to the bespoke nature of the endograft, was highlighted by the patient who was found to have been supplied with an incorrect prosthesis. This complication arose due to a miscalculation during endograft sizing from a CT scan imported from another hospital. Furthermore, it is necessary to have a broad range of ancillary equipment in the form of wires, catheters and stents to cater for unforeseen events like vessel perforation, stent misalignment or challenging catheterisation. This factor undoubtedly influenced the 100% target vessel patency in the patients who had an endograft deployed. A policy of aiming to stent all fenestrations has been advocated by other centres, and contributes to target vessel preservation.[8] A trend towards more complications in uncovered stents was observed within these data. This has resulted in a move towards the routine use of covered stents.

Table 4 Nine patients with one or more late reinterventions.

Type of reintervention	Number of patients
Renal stent angioplasty	4
Redo renal stenting	3
Iliac limb extension	2
Onyx injection for Type I endoleak	1
Inferior mesenteric artery embolisation	1
Attempted SMA angioplasty	1

These data are notable by virtue of the freedom from significant early postoperative complications. Apart from a renal stent thrombosis, no major adverse events were encountered. In particular, no patient experienced a new requirement for renal replacement therapy. The finding that significant nephropathy can be avoided has also been confirmed by many other series.[7–9] This feature is likely to be due to the multifactorial influence of stringent patient selection, careful operative technique and perioperative care.

The primary aim of aneurysm repair is to prevent death from aortic rupture. This aim has been accomplished in all patients from this series at medium term follow-up, and fenestrated endografting can be affirmed as an effective treatment of juxtarenal AAA. This is further emphasised by virtue of all but four patients demonstrating shrinkage of the aneurysm sac. Although no perioperative deaths were encountered in this small series, reported perioperative mortality rates after FEVAR are in the order of 1–4%.[7–9,12] Mortality rates should be expected to be greater than the 1.4% seen in the EVAR-1 randomised controlled trial, in the context of a procedure of greater technical complexity undertaken on frailer patients.[3] Patients in this series were unfit as reflected by the median ASA score of 3. This chronic ill-health burden is reflected in the late mortality rate of 14% within two years of AAA repair. It is, however, comparable with other series where death, during similar periods of follow-up, has ranged between 9 and 22%.[7–9] Selection for treatment must balance the risk of death from rupture against the predicted surgical mortality. It is conspicuous that in the largest reported series of FEVAR, half of the patients had AAA of 45–55 mm diameter.[9] Such patients could be anticipated to have an annual rupture risk of less than 1% compared to the reported 30-day mortality rate of 2% after FEVAR.[9,15]

The most notable feature of the present data is the rate of reintervention required during medium-term follow up. It is acknowledged that the rate of complication in the current data, in part, must reflect an unavoidable learning curve associated with a new procedure of challenging complexity. However, there appears to be an inherently high rate of complications associated with the technique that likely relates to the mechanical stresses on branch vessels stents constrained by a relatively fixed aortic endograft.

Systematic review has reported a reintervention rate of 15% after FEVAR.[12] In contrast, the present data have shown a reintervention rate of 38%. Reasons for the discrepancy are unclear. Given that conventional EVAR carries a 20% reintervention rate at four years, it may be that

other series have been over optimistic.[16] Nevertheless, Patients in the present series had a median AAA diameter of 60 mm, greater than some other reported series. Larger aneurysm diameter has been shown to be a predictor of graft related complication and reintervention after EVAR, and this is likely to hold true for FEVAR.[17] The need for reintervention will largely be influenced by the stringency of follow-up and imaging protocols. It is interesting that all patients who needed reintervention, were treated within the first year after aneurysm repair. Again, this mirrors data from conventional EVAR.[17] In contrast, FEVAR is likely to mandate a more enduring and detailed follow-up protocol to ensure target vessel patency. The current surveillance protocol, although intensive, appears effective in the diagnosis of branch vessel compromise. In particular, duplex ultrasound and plain X-rays, in combination, provide valuable information on flow dynamics within and beyond target vessels, and stent integrity and positioning respectively.

In conclusion, these data add to the accumulating evidence to support FEVAR as a feasible, safe and effective treatment in the management of high-risk patients with juxtarenal aortic aneurysm. However, the rate of graft related complications and need for reintervention is higher than previously reported at medium term follow-up. Graft durability remains uncertain and longer-term follow-up data are needed.

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Conflict of interest

None.

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